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EXAMINER	
OSTRUP, CLINTON T	
ART UNIT	PAPER NUMBER
3771	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,073	MATARASSO, HASDI	
	Examiner	Art Unit	
	CLINTON OSTRUP	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-56* is/are rejected.

7)☒ Claim(s) *28-56* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *1/21/05 & 6/26/08* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response to applicant amendment filed 6/26/08. As directed by the amendment, claims 1-27 have been cancelled. Newly added claims 28-56 are pending in this application.

Priority

2. The examiner acknowledges this application was filed as a United States National Phase Application of International Application Serial No. PCT/IL03/00599 filed July 22, 2003, which claims priority to United States Provisional Application No. 60/397,042 filed July 22, 2002.

3. If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 119(e), a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the

application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge

under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

4. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

5. The disclosure of the prior-filed application, Application No. 60/397,042, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application.

6. Claims 29, 31-32, 37-39, 42, 49, and 55 contains subject matter which was not described in the specification of 60/397,042 in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. It is also noted that figures 4, 5, 5A, 5B, 5C, 6A, 6B, 6C, 7A, 7B, 7C, and 7D were not presented in Application No. 60/397,042.

Drawings

7. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the at least one sensor must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

8. Claims 28-56 are objected to because of the following informalities:

Claim 28 is objected to because it is unclear which sensor applicant is referring to in line 20. For examination purposes, "said sensor" was read as "said at least one sensor" however, appropriate correction is required. Claims 32-33, 42-43 are objected to for analogous reasons. Claim 28 is also objected to because it is unclear if the "flow of high pressure gas" is the same as "the flow of high pressure air" described in lines 17-18.

Claim 41 is objected to because it is unclear what "the nasal air delivery unit" in lines 11-12 is referring to. For examination purposes "the nasal air delivery unit" was read as "air delivery nasal interface" as claimed in line 1.

Claim 47 is objected to because line 2 uses the phrase "air delivery unit" and lines 13-14 uses the term "nasal air delivery unit" and it is unclear if these are referring to the same or different devices. Applicant is respectfully reminded to be consistent in their terminology.

Claim 51 is objected to because it is unclear what is meant by "is having" in line 5. For examination purposes "is having" was read as "has."

Claim 53 is objected to because it is unclear if the "flow of air" in line 13 is the "flow of compressed air" in line 11.

Claims 54 & 55 are objected to because it appears to be missing the word "of" between the word "source" and the word "compressed."

Any remaining claims are objected to as depending from an objected base claim.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 28 recites the broad recitation of "administering a regulated flow of air to a person's airway", and the claim also recites "especially to a person suffering from sleep apnea" which is the narrower statement of the range/limitation.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 28, 41 & 47 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 9 of copending Application No. 10/565,363 and further in view Moa et al (5,193,532).

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to respiratory aid apparatuses using the same Venturi device.

Claim 9 of 10/565,363 claims a respiratory aid apparatus for administrating a controlled flow of respiratory gas to a user airways, the apparatus comprising:
a source of a high pressure respiratory gas (a source of high pressure air);
a nasal interface comprising at least one tubular member defining an air passage to the user's nostril when in use and at least one Venturi device (at least on Venturi device) in fluid communication with said air passage, the Venturi device comprises: a hollow member, defining a central space, having a first end open to surrounding ambient air and a second open end in fluid communication with said air passage; and a first inlet port opening into said central space, the inlet is configured to direct compressed respiratory gas entering said central space toward the second end; and a low cross-section flexible tubing (at least one flexible thin tubing) connecting between the source of high pressure respiratory gas and said inlet of said Venturi device; wherein the nasal interface unit has at least one sensor (at least one sensor) for detecting a respiratory cycle of the user and with at least one controller (a control unit) for controlling the pressure of compressed gas entering the interface unit via the first inlet port, in accordance with said sensor.

Although claim 9 of 10/565,363 claims a nasal interface comprising at least one tubular member defining an air passage to the user's nostril when in use, it lacks a detailed description of a nasal adapter as claimed in claims 28, 41 and 47.

Moa discloses a Venturi nasal interface device used to deliver respiratory gas to a user with nasal adapters (24) attachable to a person's nostril. See: col. 3, lines 32-35 and figure 6.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have added the nasal adapters to the end of the tubular member claimed in claim 9 of 10/565,363 in order to provide adapters made of an elastic material that can be more comfortably and securely placed in a nostril of a user.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. **Claims 28-29, 33-36, 41, 43-44, 47-48 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moa et al., (5,193,532) and further in view of Boussignac (6,363,935).**

Moa discloses a portable respiratory aid system (figure 6) for administrating a regulated flow of air (continuous positive airway pressure) to a person's airway, the respiratory aid system comprising: a source of high pressure air (col. 1, lines 62-68.) ; an air delivery nasal interface (figure 6), the nasal air delivery interface comprising: at least one nasal adaptor (24) attachable to a person's nostril, the at least one nasal

adaptor comprising an air passage (10); at least one Venturi device (figures 1-3), the at least one Venturi device comprising a central space (figures 1-3), a first (10) and a second open ends (11), and a first inlet (13) which opens into said central space (figures 1-2), wherein the first open end (10)is open to surrounding ambient air and the second open end (11) is in fluid communication with the air passage of said at least one nasal adaptor, and wherein said first inlet (13) is configured (a tube can be connected to 13) for receiving a flow of high pressure gas and for directing said flow of high pressure gas toward said second open end (figure 1); however, Moa lacks a sensor for monitoring breathing, a detailed description of the size of the tubing uses to connect the first inlet (13) to a high pressure source of air; and a control unit operably connected to the sensor for regulating the flow of high pressure air in accordance with the monitored breathing.

Boussignac teaches a Venturi device (2) of various sizes for delivering respiratory gas to a patient with a pressure sensor for detecting overpressure. The tube sizes of the device made by Boussignac overlap the sizes of the tubes as claimed in claim 6. The sensor taught by Boussignac is a pressure sensor that detects if overpressure occurs in the respiratory tract of the patient and that the sensor is located in the interface unit. See: col. 4, lines, lines 16-18; col. 5, line 25 – col. 6, line 24 and figure 1. Boussignac teaches using a control unit (22) to control the supply of gas via a pressure detector/sensor (33) which is able to detect the changes from inhalation to exhalation in the patient's breathing. See: col.5, lines 25-40. Moreover, Boussignac describes device (1) as including a tube (4) which adapts to the morphology of a patient

and specifically describes how the device can constitute a nasal probe. See: col. 3, line 55 - col. 4, line 3.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have added a pressure sensor that is operably connected to a control unit as taught Boussignac to the nasal CPAP device disclosed by Moa because of the reasonable expectation of obtaining a respiratory device that uses common medical tubes and prevents overpressure of the respiratory track of a patient.

Regarding claim 29, Boussignac teaches tube sizes that overlap those claimed and that the pressure can be optimized from the gas source. See: col. 5, lines 17-20 & lines 53-63. Thus, the output pressure in the range of 2-6 Atmospheres is a modification that would be obvious to a skilled artisan and the pressure level selected would depend greatly upon the age, size and condition of a patient.

Regarding claims 33-36, Boussignac teaches a pressure sensor/detector (33) that is operably connected to a control unit (22) which is then operably connected to a control valve (30) which can be in an open (on) closed (off) which regulate the gas flow to the patient. See: figure 1 and col. 5, lines 20-40.

Regarding claim 41, Moa discloses an air delivery nasal interface (figure 6) with at least one nasal adaptor (24) attachable to a person's nostril, the at least one nasal adaptor comprising an air passage (figures 1-3); at least one Venturi device (figures 1-3), the at least one Venturi device comprising a central space (figures 1-3), a first (10) and a second (11) open ends, and a first inlet (13) which opens into said central space,

wherein the first open end (10) is open to surrounding ambient air and the second open end (11) is in fluid communication with said air passage of the at least one nasal adaptor (24), and wherein said first inlet (13) is configured for receiving a flow of high pressure gas (it can be connected to a tube) and for directing said flow of high pressure gas toward said second open end (figure 1); and Boussignac teaches the least one sensor (33) for monitoring breathing of a person using the nasal air delivery unit. See: Boussignac, col.5, lines 25-40.

Regarding claims 43-44, Boussignac teaches a pressure sensor/detector (33) that is operably connected to a control unit (22) which is then operably connected to a control valve (30) which can be in an open (on) closed (off) which regulate the gas flow to the patient. See: figure 1 and col. 5, lines 20-40.

Regarding claim 47, Moa discloses an air delivery nasal interface (figure 6) with two air delivering units (col. 3, lines 12-17), each for delivering a flow of air to one of a person's nostrils, wherein each of said two air delivery units has a nasal adaptor (24) attachable to a person's nostril, the nasal adaptor comprising an air passage (11); and a Venturi device (figures 1-3), the Venturi device comprising a central space (figures 1-3), a first (10) and a second (11) open ends, and a first inlet (13) which opens into said central space, wherein the first open end (10) is open to surrounding ambient air and the second open end (11) is connected to the air passage of said nasal adaptor (24), and wherein said first inlet (13) is configured to receive a flow of high pressure respiratory gas (it can be connected to a tube) and to direct said flow of high pressure respiratory gas toward said second open end (figure 1); and Boussignac teaches a

pressure detector/sensor (33) for monitoring breathing of a person using the nasal air delivery unit.

Regarding claim 48, Moa discloses a comprising a common interface inlet (20) in fluid communication with said first inlets (13) of the two air delivering units (col. 3, lines 12-17).

Regarding claim 53, Moa discloses a method of treating spontaneous breathing using a CPAP device (which is the most common method of treating sleep apnea) by administering a controlled flow of air (via a CPAP device) to a patient that has their ability to breath impaired), in accordance with the real-time needs of the person (the ejector action counteracts the tendency to decrease pressure during the inspiration phase), by connecting a CPAP device to an inlet port (20) of an air delivery nasal interface (figure 6) wherein the air delivery nasal interface comprises an at least one Venturi device (figures 1-3) interposed between said inlet port (20) and at least one nasal adaptor (24) configured to be attached to a person's nostril, the at least one Venturi device having a first open (10) end which opens to ambient air and a second open (11) end which opens into an air passage (figures 1-3) in said nasal adaptor (24); and monitoring the breathing of said person (see: col. 3, lines 18-23); and Boussignac teaches delivering a flow of compressed air from a source of compressed air via thin tubing to an air delivery device; and regulating the flow of air in accordance with the monitored breathing.

Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have used a CPAP device to treat sleep apnea, using the CPAP nasal interface disclosed by Moa and using the thin tubing to connect the nasal interface to a high pressure gas supply as taught by Boussignac, in order to connect the CPAP device to the nasal interface. Since CPAP devices are the most common devices used for treating sleep apnea and Moa disclosed using his device to treat breathing disorders, it would be obvious to one having ordinary skill in the art to have used the CPAP device of the combined references to treat sleep apnea.

Regarding claim 56, this claim reads on a patient that has been diagnosed with sleep apnea (detection of a breathing disorder) turning off the CPAP machine (in the morning after a patient wakes up turning off the supply of air upon detection of a regular non-obstructive breathing) and then turning it on again before going to bed that evening (turning on the supply of air upon detection of a breathing disorder). Thus, the method of treating a patient with a breathing disorder disclosed by Moa meets the limitations of claim 56.

14. **Claims 30, 40, 45-46, 50, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moa et al., (5,193,532) in view of Boussignac (6,363,935), as applied to claims 28, 41, and 47 above, and further in view of Sherrod (5,979,444).**

The combined references disclose all the limitations of claims 30, 40, 45, 50 and 54 except the high pressure air as being in a portable container and a Venturi device having a second inlet which opens into the central space and wherein the second inlet

is configures for receiving a flow of high pressure gas for directing the flow of high pressure gas toward the first open end.

Sherrod discloses a respiratory aid apparatus (Figures 1-2A) for administrating a controlled flow of respiratory gas to a user airways, the apparatus comprising a portable container of a high pressure respiratory gas (18) and a Venturi device (28), the Venturi device comprises: a hollow member, defining a central space (46), having a first end open to surrounding ambient air (36) and a second open end directed toward the user airways (64); and a first inlet port opening into said central space(44), the inlet is configured to direct compressed gas entering said central space toward the second end; and a low cross-section flexible tubing (20 & 24) connecting between the source of high pressure respiratory gas and said inlet of said Venturi device. See: figures 1-2A. Sherrod discloses a Venturi device comprising a second inlet port opening (48) into said central space and wherein said second inlet is configured to direct compressed gas entering the central space toward the first end for assisting removal of air from the user's airways.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have added a second inlet port, as taught by Sherrod, to the nasal interface device disclosed by Moa to facilitate exhalation of respired air.

Regarding claim 46, Sherrod discloses a regulator valve (22) operably interposed between said first and second inlets wherein the controllable is configured to allow direction of flow to either the first inlet or to the second inlet. See: figure 1.

15. **Claims 31 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moa et al., (5,193,532) in view of Boussignac (6,363,935), as applied to claim 28 above, and further in view of Hill et al., (US 2002/0096174).**

The combined references disclose all the limitations of claims 31 & 37 except the oil-less air compressor.

Hill teaches a portable oxygen concentrator system wherein the compressor is preferably an oil-less compressor to prevent the possibility of oil or grease from entering the air flow path. See: page 3, [0036].

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have used an oil-less compressor, as taught by Hill et al., as the high pressure gas source disclosed by Boussignac in order to provide a gas source that would prevent oil or grease from entering a patient's respiratory tract.

16. **Claims 49, 51 & 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moa et al., (5,193,532) in view of Boussignac (6,363,935), as applied to claim 28 above, and further in view of Goldstein (5,752,510)**

The combined references disclose all the limitations of claim 49 except the two air delivery units being pivotally mounted on a flexible elongated connector to be placed between the mouth and a nose of a user.

Goldstein teaches an apparatus that has a two air delivery units (holes in 21) that are pivotally mounted to a flexible elongated connector (23) that is configured to be placed between the mouth and the nose of a user. See: figures 1-3. Goldstein teaches that the device is useful for delivering an air supply because it provides a means for

stabilizing and supporting the nasal tubes and maintains the user's lower jaw in a forward. See: col. 2, lines 15-59 and figures 1, 2, and 3.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified air nasal air delivery device disclosed by the combined references by utilizing the delivery unit as taught by Goldstein to form a breathing device that alleviates many sleeping disorders by providing air to a user while maintaining the user's jaw in a forward position.

Regarding claim 51 Moa discloses an air delivery nasal interface with two Venturi devices wherein each of said two Venturi devices have hollow member defining a central space (figures 1-3), the hollow member is having a first (10) and a second open (11) ends; and a first inlet (13) which opens into said central space, said first inlet is connectable to a thin tubing (13 can be connected to a tube via 20); wherein the first open end (10) is open to surrounding ambient air and the second open end (11) is provided with a nasal adaptor (24) configured to be attached to a person's nostril, and wherein said first inlet (13) is configured to receive a flow of high pressure respiratory gas via the thin tubing and to direct said flow of high pressure respiratory gas toward said second open end (figure 1) and Goldstein teaches two nasal delivery devices (22) pivotally mounted on opposite ends of a flat flexible member (16) configured to be placed between mouth and nose.

Regarding claim 52, Boussignac teaches a pressure sensor (33) for monitoring breathing.

17. **Claims 32, 38, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moa et al., (5,193,532) in view of Boussignac (6,363,935)and further in view of Miles (5,353,788)**

The combined references disclose all the limitations of claims 32, 38 and 42 except the sensor being a sound transducer or temperature detector and the control unit comprising a programmable microprocessor and a memory device.

Miles discloses a control and monitoring system for determining CPAP pressure for apnea treatment. The reference teaches using thermistors, thermocouplers, microphones, and sensors for detecting and monitoring chest and abdominal respiration and using a programmable monitoring and control unit comprising a programmable microprocessor and a memory device (IBM-PC compatible computer). See: col. 7, lines 33-57.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to added sensors for monitoring the temperature, sound and body movement of a patient, as taught by Miles, to the CPAP delivery device disclosed by the combined references in order to provide a controlled, monitored method of delivering CPAP to a patient.

18. **Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moa et al., (5,193,532) in view of Boussignac (6,363,935) and Sherrod (5,979,444), as applied to claims 47 & 50 above, and further in view of Hill et al., (US 2002/0096174).**

The combined references disclose all the limitations of claim 55 except the oil-less air compressor.

Hill teaches a portable oxygen concentrator system wherein the compressor is preferably an oil-less compressor to prevent the possibility of oil or grease from entering the air flow path. See: page 3, [0036].

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have used an oil-less compressor, as taught by Hill et al., as the high pressure gas source disclosed by Boussignac in order to provide a gas source that would prevent oil or grease from entering a patient's respiratory tract.

Response to Arguments

19. Applicant's arguments with respect to claim 28-56 have been considered but are moot in view of the new ground(s) of rejection.

The substitute specification filed 6/26/08 is in compliance with 37 CFR 1.125 and has been entered.

Conclusion

20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Genger et al. (WO 02/062413 A2); Genger et al. (7,080,645); and Genger et al., (US 2004/0016432A1); Glenn et al (3,581,742); Hofstetter et al. (5,975,077); and Ellis (6,561,188).

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771